

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CELLECTIS S.A.,

Plaintiff,

v.

PRECISION BIOSCIENCES, INC.,

Defendant.

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C.A. No. 10-1033-SLR

JURY TRIAL DEMANDED

**DEFENDANT PRECISION BIOSCIENCES, INC.'S
ANSWER AND COUNTERCLAIMS**

Pursuant to Rules 8 and 12 of the Federal Rules of Civil Procedure, Defendant Precision BioSciences, Inc. ("Precision") responds to the allegations contained in the Complaint of Plaintiff Cellectis S.A. ("Cellectis") as follows:

THE PARTIES

1. Precision is without information or knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 1 of the Complaint.
2. Admitted.

NATURE OF THE ACTION

3. Paragraph 3 of the Complaint contains a description of the lawsuit by Cellectis to which no response is required. To the extent Paragraph 3 contains allegations of fact, Precision denies such allegations.

JURISDICTION AND VENUE

4. Paragraph 4 consists of conclusions of law to which no response is required.

5. Paragraph 5 consists of conclusions of law to which no response is required. Precision denies that it has ever infringed any claim of U.S. Patent No. 7,842,489 (“the ‘489 Patent”).

6. Paragraph 6 consists of conclusions of law to which no response is required.

BACKGROUND
Collectis’s Patent-In-Suit

7. Precision admits that the ‘489 Patent was issued by the United States Patent and Trademark Office (“the PTO”) on November 30, 2010 and that a copy of the ‘489 Patent was attached to the Complaint. Precision denies all other allegations contained in Paragraph 7 of the Complaint.

8. Paragraph 8 consists of a characterization of the science and technology of Collectis’s patent to which no response is required. To the extent a response is required, Precision denies the accuracy of Collectis’s characterization.

9. Paragraph 9 consists of a characterization of Collectis and its purported work to which no response is required. To the extent a response is required, Precision denies the accuracy of Collectis’s characterizations.

10. Paragraph 10 consists of a characterization of the ‘489 Patent to which no response is required. To the extent a response is required, Precision denies the accuracy of Collectis’s characterizations.

Precision’s Alleged Infringing Activities

11. Precision admits that it makes certain endonucleases that may be used in certain methods of preparing transgenic organisms (including plants) using a technology that it refers to as the Directed Nuclease Editor™ (DNE) and that the technology allows the targeting of site-directed breaks in DNA that can be used to effect certain desired modifications to the genomes of

certain organisms. Precision denies the accuracy of any remaining characterizations or allegations contained in Paragraph 11 of the Complaint.

12. Denied.

13. Denied.

COUNT I

ALLEGED PATENT INFRINGEMENT OF THE '605 PATENT

14. Precision acknowledges that Paragraphs 1-13 of the Complaint are incorporated by reference. Precision incorporates by reference its responses to Paragraphs 1-13 of the Complaint as stated above.

15. Denied.

16. Denied.

17. Denied.

DEFENSES

FIRST DEFENSE

18. Collectis is not entitled to any relief against Precision because Precision is not infringing and has not infringed, has not induced infringement of, and has not contributed to the infringement of any claim of the '489 Patent.

SECOND DEFENSE

19. One or more of the claims of the '489 Patent are invalid and/or unenforceable for failing to meet one or more of the requisite statutory and decisional requirements and/or conditions for patentability under Title 35 of the United States Code, including without limitation, 35 U.S.C. §§ 102, 103 and 112.

COUNTERCLAIMS¹

Precision BioSciences, Inc., for its counterclaims against Collectis SA, alleges as follows:

PARTIES

1. Counterclaim-plaintiff Precision BioSciences, Inc. ("Precision") is a corporation organized and existing under the laws of Delaware, with its principal place of business in Durham, North Carolina.

2. Upon information and belief, counterclaim-defendant Collectis S.A. ("Collectis") is a corporation organized and existing under the laws of France, with a principal place of business in Paris, France.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

4. Collectis is subject to personal jurisdiction in this District, at least by virtue of its institution of its lawsuit against Precision for alleged infringement of the '489 Patent.

5. Venue for these counterclaims is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTS AND BACKGROUND

Competition Between Collectis and Precision

6. Precision is a privately held, start-up biotechnology company that was founded in 2006 and is based in Research Triangle Park, North Carolina. Precision develops and

¹ Precision does not believe that the District of Delaware is the appropriate venue for Collectis's lawsuit or for Precision's counterclaims against Collectis, but Precision asserts its counterclaims here to preserve its rights in this action.

commercializes therapeutics and services that enable site-specific genome modifications within a living organism using rationally engineered endonucleases. This capability allows for insertion, removal, or modification of DNA at nearly any gene in nearly any organism. Precision is using its technology to enable the development of treatments for genetic and viral diseases, the creation of greatly needed new crops and fuel sources, and the construction of new tools for biomanufacturing and diagnostic applications.

7. Upon information and belief, Collectis is a publicly traded biotechnology company that was founded in 2000 in France. Collectis designs and markets its own endonucleases that are also used for the purpose of enabling targeted modifications to DNA. Collectis's endonucleases are used in research, biomanufacturing, agrobiotechnology and therapeutic sectors. Upon information and belief, Collectis has more than 50 agreements with pharmaceutical entities, seed producers, and biotechnology companies, has formed over 20 academic research partnerships, and has secured over 70 million Euros (more than \$94 million) in funding since its inception. Upon further information and belief, Collectis has a share in excess of two-thirds of the worldwide market for engineered endonucleases used in genetic recombination and modification.

8. Although Collectis is a more mature company with more funding and greater sales, Precision and Collectis today compete for the same customers to provide their respective endonucleases for use in genetic engineering.

Prior Litigation Instituted by Collectis Against Precision

9. In March of 2008, shortly after Precision announced its first major commercial relationship with a leading biotechnology/agricultural interest, Collectis sued Precision in the Eastern District of North Carolina for infringement of two patents. *See Collectis S.A. v.*

Precision BioSciences, Inc., E.D.N.C. Docket No. 5:08-CV-00119-H2 (“Initial Lawsuit”).

Precision does not make, use, sell, or offer to sell endonucleases practicing the claims of the patents asserted in the Initial Lawsuit, and did not do so previously. In addition, Precision asserted that the patents asserted against it in the Initial Lawsuit were invalid as anticipated or obvious in light of undisclosed prior art references, several of which were in the possession of the lead inventor and the prosecuting attorneys but were not properly submitted to the United States Patent and Trademark Office (“PTO”) during prosecution. Precision also asserted that the failure to disclose these material prior art references constitutes inequitable conduct.

Nevertheless, Cellectis pressed this Initial Lawsuit in an apparent effort to hinder its smaller competitor, Precision, with the costs and burdens of litigation.

10. In the Initial Lawsuit, Cellectis engaged in dilatory tactics in document discovery and depositions, including, for example, issuing a tardy and overburdensome third-party subpoena for documents and deposition testimony from one of Precision’s key customers. Upon information and belief, Cellectis’s litigation tactics were calculated to exact the maximum possible negative financial and business impact against Precision by forcing Precision to expend large sums of money in attorneys’ fees and by seeking to inconvenience or harass Precision’s customers.

11. While the litigation was ongoing, Precision requested *inter partes* reexamination of the patents-in-suit. The PTO granted Precision’s reexamination request, rejecting all asserted claims of each of the patents-in-suit as anticipated or obvious in light of the previously undisclosed, material prior art submitted by Precision.

12. Following the PTO’s grant of Precision’s request for reexamination of both patents and the rejection of all asserted claims, Precision filed a motion to stay the litigation

pending final resolution and appeal of the PTO's decision on reexamination. After more than two-and-a-half years of costly litigation, and with the issues of claim construction fully briefed and opening expert reports about to be served, the court granted Precision's requested stay pending the final outcome of reexamination and appeal.

The '489 Patent and the New Lawsuit by Collectis Against Precision

13. The application that led to the '489 Patent-in-suit was filed on February 23, 2010, during the pendency of the Initial Lawsuit instituted by Collectis against Precision and specifically following (1) the publication of an article in November of 2009 describing collaborative work undertaken by Precision and one of its customers using an engineered endonuclease of Precision's proprietary design called LIG-3,4 and (2) the depositions of Precision's scientists and Precision's customer and collaboration partner regarding work with the LIG-3,4 endonuclease.

14. The '489 Patent issued on November 30, 2010.

15. Collectis claims to be the assignee and patent holder of the '489 Patent.

16. On November 30, 2010, the same day the '489 Patent issued, Collectis sued Precision, alleging infringement of that patent.

17. The claims of the '489 Patent seem to be intentionally directed to an endonuclease having the precise characteristics of the LIG-3,4 endonuclease as described in the November 2009 publication and during the depositions of Precision's scientists and of Precision's customer.

**PRECISION DOES NOT INFRINGE THE CLAIMS OF THE '489 PATENT, AND
THOSE CLAIMS ARE INVALID IN ANY EVENT**

18. In spite of Precision's prior work with the LIG-3,4 endonuclease, Precision has not made, used, sold, offered for sale, or imported the LIG-3,4 endonuclease or any other endonuclease purported to be covered by the claims of the '489 Patent since before Precision

learned of the '489 Patent on the day of its issuance as a result of being sued by Collectis. Likewise, since well before learning of the '489 Patent on the day of its issuance, Precision has not engaged in any activity that would induce any of its customers to undertake conduct that would, in light of its issuance, infringe any claims of the '489 Patent, nor has Precision contributed in any manner toward any infringement of any claim of the '489 Patent.

19. On December 7, 2010, after learning of Collectis's filing of the new lawsuit, counsel for Precision contacted counsel for Collectis and stated that Precision was not making, using, selling, or offering for sale the LIG-3,4 endonuclease or any other endonuclease that would infringe the claims of the '489 Patent. Similarly, Precision's counsel stated that Precision had undertaken no activity to induce or contribute to the infringement of any claim of the '489 Patent since that patent issued. Accordingly, in light of Precision's non-infringement, Precision's representations, and the absence of any good faith dispute or controversy in regard to that issue, Precision's counsel requested that Collectis withdraw its lawsuit alleging infringement of the '489 Patent by Precision. At the request of Collectis's counsel, on December 15, 2010, counsel for Precision sent a letter confirming in writing the representations made during the December 7 telephone conference.

20. On December 31, 2010, Collectis's counsel requested certain further information it purported was necessary to evaluating Precision's representations that it does not infringe. By letter dated January 20, 2010, Precision provided a more detailed statement answering Collectis's specific questions and reiterating that Precision does not infringe, and has never infringed, the claims of the '489 Patent, either directly or indirectly, and that Precision has no intention of infringing those claims moving forward.

21. In addition, the specification of the '489 Patent does not provide an enabling disclosure for the claims of that patent, nor does the specification indicate the inventors were in possession of the claimed inventions. The claims of the '489 Patent are invalid on this basis and/or other bases under 35 U.S.C. §§ 102, 103, and 112.

22. Despite Precision's oral and written representations, Collectis continues to maintain this patent infringement action. In the face of Precision's oral and written representations and in the absence of any evidence or good faith belief that the allegations made in the Complaint are true, Collectis' continued pursuit of this action is objectively baseless and undertaken with an intent to interfere with Precision's business, not to enforce any legitimate intellectual property rights.

23. Given that Collectis has sued Precision and refuses to drop that lawsuit in the face of Precision's representations of non-infringement, an actual case or controversy exists between the parties concerning the infringement and validity of one or more of the claims of the '489 Patent.

**COLLECTIS HAS ENGAGED IN ANTICOMPETITIVE AND UNFAIR CONDUCT
THAT HAS INJURED AND WILL INJURE PRECISION AND THREATENS TO
ELIMINATE COMPETITION IN THE ENGINEERED ENDONUCLEASES MARKET**

Relevant Market

24. The relevant product market affected by Collectis's anticompetitive conduct is the market for engineered meganucleases for use in genetic modification and recombination (including crop science, research, and therapeutic applications).

25. The relevant geographic market is worldwide.

26. Significant barriers to entry exist in the relevant market, including large capital costs and advanced technical know-how, such that, if Collectis were to limit or destroy

Precision's ability to compete in this market by subjection Precision to the high costs of litigation via its improper patent infringement action against Precision, Collectis's monopoly power in the relevant market will increase.

Collectis's Monopoly Position

27. Upon information and belief, Collectis is the dominant supplier of engineered endonucleases for use in genetic modification and recombination, with greater than two-thirds of the relevant market share. Upon information and belief, because of its dominant position, Collectis is able to raise and maintain prices above a competitive level. If it is able to limit or destroy competition from Precision, such ability will continue or increase.

28. Upon information and belief, Collectis' continued maintenance of this patent infringement action in light of Precision's oral and written representations and in the absence of any evidence or good faith belief to the contrary is motivated by an intent to preserve or obtain a monopoly in the relevant market for engineered endonucleases.

Anticompetitive Effects of Collectis's Misconduct

29. Collectis's sham litigation has caused and continues to cause injury to Precision by subjecting it to the costs and burdens of defending itself against a patent that it does not infringe. Collectis's baseless lawsuits also cast an artificial pall over Precision's business and its ability to form and sustain relationships with its customers and potential customers.

30. Should Collectis be allowed to continue its misconduct and succeed in its objective of weakening or eliminating Precision as a competitor by maintaining its improper infringement suit, Collectis will be able to raise prices above a competitive level as a result of the absence of meaningful competition in the relevant market.

31. Collectis's improper conduct has had and will continue to have substantial anticompetitive effects in the relevant market for engineered endonucleases for use in genetic modification and recombination.

COUNT ONE

(Non-Infringement of the '489 Patent)

32. Precision repeats and re-alleges the allegations of the preceding Counterclaim Paragraphs 1-31 as if fully set forth herein.

33. Precision has not directly or indirectly infringed and is not directly or indirectly infringing the '489 Patent.

34. Precision is entitled to a declaratory judgment that it has not infringed and is not infringing the '489 Patent.

COUNT TWO

(Invalidity of the '489 Patent)

35. Precision repeats and re-alleges the allegations of the preceding Counterclaim Paragraphs 1-34 as if fully set forth herein.

36. One or more claims of the '489 Patent are invalid for failing to meet one or more of the requisite statutory and decisional requirements and/or conditions for patentability under Title 35 of the United States Code, including without limitation, §§ 102, 103, and/or 112.

37. Precision is entitled to a declaratory judgment that the claims of the '489 Patent are invalid.

COUNT THREE

(Violation of Section 2 of the Sherman Act, 15 U.S.C. § 2 – Monopolization)

38. Precision repeats and re-alleges the allegations of the preceding Counterclaim Paragraphs 1-37 as if fully set forth herein.

39. During the relevant period, Collectis has offered for sale and sold engineered endonucleases both in the United States and abroad.

40. Collectis' illegal conduct has substantially affected interstate and foreign commerce.

41. Collectis possesses monopoly power in the relevant market, maintaining a dominant share of a market with high entry barriers.

42. By attempting to enforce a patent after becoming aware of information that Precision has not infringed and does not infringe the '479 Patent, Collectis has maintained an objectively baseless lawsuit in an attempt to interfere directly with Precision's business. Upon information and belief, Collectis has done so with the specific intent to unlawfully monopolize the engineered endonuclease market.

43. As a direct and proximate cause of Collectis's anticompetitive conduct, Precision has suffered injury to its business and its property and is threatened by the imminent loss of profits, loss of customers and potential customers, and loss of goodwill. Precision has incurred, and will continue to incur, substantial costs in defending against Collectis's baseless actions.

44. Collectis has acquired, maintained and enhanced its monopoly power in the relevant worldwide market for engineered endonuclease for use in genetic modification and recombination in violation of Section 2 of the Sherman Act (15 U.S.C. § 2).

COUNT THREE

(Violation of Section 2 of the Sherman Act, 15 U.S.C. § 2 – Attempted Monopolization)

45. Precision repeats and re-alleges the allegations of the preceding Counterclaim Paragraphs 1-44 as if fully set forth herein.

46. By attempting to enforce a patent after becoming aware of information that Precision has not infringed and does not infringe the '479 Patent, Collectis has maintained an objectively baseless lawsuit in an attempt to interfere directly with Precision's business. Upon information and belief, Collectis has done so with the specific intent to acquire monopoly power in the relevant worldwide market for engineered endonuclease for use in genetic modification and recombination.

47. Because of Collectis' dominant position in the relevant market, the high entry barriers in the market, and Precision's status in a market with few other competitors, there is a dangerous probability that Collectis will succeed in this attempt.

PRAYER FOR RELIEF

WHEREFORE, Precision requests entry of judgment in its favor and against Collectis as follows:

- A. Dismiss Collectis's Complaint with prejudice, denying all relief to Collectis;
- B. Enter judgment in favor of Precision and against Collectis;
- C. Declare that Precision has not infringed and does not infringe any claim of the '489 patent;
- D. Declare that the asserted claims of the '489 patent are invalid;
- E. Adjudge and decree that Collectis is liable for violation of Section 2 of the Sherman Act, 15 U.S.C. § 2;
- D. Find that this is an exceptional case and award Precision its costs (including expert fees), disbursements, and reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and
- E. Award Precision such other relief as the Court may deem appropriate and just under the circumstances.

DEMAND FOR JURY TRIAL

Defendant Precision respectfully demands a trial by jury on all issues so triable.

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on January 20, 2011, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on January 20, 2011, the attached document was electronically mailed to the following person(s)

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